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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/437,726	11/09/1999	WILLEM P. C. STEMMER	02-029220US	8363

20350 7590 07/16/2002

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/437,726

Applicant(s)

STEMMER ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Continued Prosecution Application

2. The request filed on 19 June 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/437,726 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 27-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is well settled that to define a product, such as nucleic acid, not by its chemical or physical properties, but in terms of its functional characteristics, does

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not constitute an adequate written description of the product.¹ The method of claim 27 is to result in the production of a nucleic acid that has been defined as encoding a protein of an undefined amino acid sequence and wherein the amino acid sequence is to demonstrate “enhanced Rubisco carboxylation activity” wherein said activity is determined by an unspecified method. Such a description of the ultimate product where as here the polynucleotide has been defined in terms of how it is to function, and not in terms of its chemical and physical properties, does not constitute an adequate written description of the end product such that one of skill in the art would readily recognize that they have produced the intended product.

5. Claim 27 and dependent claims 28-32 specifically refer to “the plurality of parental polynucleotide species” as providing a reference point for comparison. The claims does not define “the plurality of parental polynucleotide species” in terms of their chemical and physical properties, but rather, in terms of their ability to encode a protein that has Rubisco activity- an functional characteristic. While dependent claims 33-35 require “the plurality of parental polynucleotide species” to encode a specific subunit, such a definition or limitation is not considered to constitute a chemical or physical description of the reference material, but rather, a description of the functional characteristic of the reference material. As a consequence one would not readily be able to determine what constitutes their reference polynucleotide sequences and from which an appropriate comparison could be made.

6. Claim 36 also has defined the “marker gene” not in terms of its chemical or physical properties, but in terms of its functional characteristics. Claim 37, which depends from claim 36, fails to overcome these issues and is similarly rejected.

¹ *University of California v. Eli Lilly and Co.* (CA FC, July 1997) 43 USPQ2d 1398.

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7. Applicant is urged to amend the claimed method such that the reference polynucleotide species and final product are defined in terms of their chemical and /or physical properties and not in terms of how they are to function.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 27-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 27 is indefinite with respect to what constitutes the metes and bounds of “significantly enhanced.” For example, is it statistically significant or is some other threshold to be applied? Claims 28-37, which depend from said claim 27, fail to overcome this issue and are similarly rejected.

11. Claim 28 is indefinite with respect to what constitutes “higher.”

12. Claims 29 and 32 are indefinite with respect to what constitutes the metes and bounds of “greater than.”

13. Claims 30 and 31 are indefinite with respect to the metes and bounds of “less than.”

14. Claim 30 is confusing as to how an enzyme has a “velocity” of carboxylation activity.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 27 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Minshull et al., (WO 97/35966), Spreitzer (Anna. Rev. Plant Physiol. Plant Mol. Biol.) and Wolter et al. (PNAS, USA).

18. Minshull et al., disclose a method of recursive sequence recombination or gene shuffling whereby a gene of interest is evolved (page 4). The method comprises steps whereby the shuffled or recombined gene is screened and selected. The method is applicable to the shuffling of a plurality of genes as well as to the evolution of but a single gene (page 13). At pages 21-33 Minshull et al., disclose the method of shuffling as it relates to the evolution for a specific gene where enhanced catalytic properties with a substrate is desired. Method of screening and selection of clones is also disclosed.

19. Minshull et al., do not teach the screening of genes for enhanced Rubisco activity explicitly, but do teach a method that is broadly applicable to the shuffling of genes and the selection of genes with the desired characteristics.

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20. Spreitzer discloses the genetic structure of Rubisco and its function. At pages 416-418 the aspect of selecting for mutants of Rubisco is disclosed.

21. Wolter et al., disclose the shuffling of Rubisco gene during evolution.

22. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to have adapted the method of Minshull et al., so as to allow for the shuffling and screening of polynucleotides sequences that encode Rubisco with desired properties. Such motivation is base on the aspect that the genes for Rubisco had not only been isolated and characterized and were known to undergo shuffling naturally, but that the gene product, Rubisco, was of long and intense interest in the art and the isolation of desirable mutant clones continues to this day to be of much interest. In view of the explicit teachings by Spreitzer to find desirable clones, and in view of the broad applicability of the method of Minshull et al., to the shuffling of gene(s) and screening and selection of desired clones, the ordinary artisan would have been highly motivated and would have also had a reasonable expectation of success.

23. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Response to arguments

24. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). At page 7 of the response argument is presented that the "[a] skilled artisan would regard the teaching of Wolter reference as essentially irrelevant with respect to the obviousness of the claimed invention." Argument of

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an attorney does not take the place of evidence in establishing what one of skill in the art would or would not have thought or considered. Acknowledgement is made of applicant having provided copies of journal articles in association with their response. It is noted that journal articles do not take the place of sworn statements and that such sworn statements have not been timely provided. Further, the articles provided have not been cited on a PTO-1449, nor accompanied with the requisite petition, certification and fee and accordingly, have not been considered on the merits .

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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27. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
July 15, 2002